

REMARKS

Applicant respectfully requests further examination and reconsideration in view of the above amendments and arguments set forth fully below. Claims 1-14, 17-24 and 41-49 were previously pending in the instant application. Within the previous Office Action, Claims 1-14, 17-24 and 41-49 have been rejected. By way of the above amendment, Claims 1-4, 11, 17, 23 and 41 have been amended. Claims 1-14, 17-24 and 41-49 are still pending in this application.

Rejections Under 35 U.S.C. § 112

Claims 41-49 have been rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Within the Office Action it is specifically stated that the originally filed disclosure is silent on the lasers producing the same wavelength. For all the reasons discussed in the response to the previous Office Action, the Applicants respectfully disagree. However, in order to further the prosecution of this Application, Claim 41 has been amended to remove the recitation of "a same wavelength." Claims 42-49 are dependent on the independent claim 42.

Claims 2-5, 11-14, 17-23 and 49 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Within the Office Action it is specifically stated that is not clear in Claims 2 and 49 what is meant by "arm feature." Claim 2 has been amended, as suggested within the Office Action, to recite "an articulated arm feature." Claim 49 already recited "an articulated arm feature."

Regarding Claims 11 and 17 it is stated within the Office Action that it is unclear what is meant by two or more lasers combined in an alternating pattern or fashion to produce a plurality of coagulative laser pulses." Claim 11 has been amended to recite a laser source having two or more pulsed lasers for generating pulses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. Claim 17 has been amended to recite a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to alternate between laser pulses of the first laser and the second laser to form a single laser output by a

combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. Thus, in Claims 11 and 17 it is abundantly clear that the laser output comprises pulsed laser light from each of the lasers. Claims 12-14 depend on the independent Claim 11, and Claims 18-23 dependent on the independent Claim 16.

Rejections Under 35 U.S.C. § 102

Within the previous Office Action, Claims 1, 2, 11 and 17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer"). The Applicants respectfully traverse this rejection. No description to the teachings of Dwyer or detailed reasons for the rejection is given within the Office Action.

Dwyer teaches a laser device that switches between a first laser beam with a first set of laser conditions and a second laser beam with a second set of laser conditions. Dwyer teaches that by manipulating the optics within the cavity of a Nd:YAG laser, the most probable lasing transition producing laser light 1.06 microns, can effectively be shut off such that lasing can occur to produce laser light at 1.3 microns. [Dwyer, Abstract] In other words, Dwyer teaches a laser device with a tunable laser cavity for switching between two lasing conditions and thus producing two wavelengths, only one of which is generated under any one set of laser conditions.

Dwyer also teaches that a system can have two lasers with one of the lasers operating at 1.06 microns and the other laser operating at 1.3 microns, such that a surgeon can switch between the two lasers for cauterizing and cutting, respectively. However, Dwyer does not teach using one or more pulsed lasers, wherein pulses from each of the pulsed lasers are combined into a single laser output to produce conditions for non-ablation or coagulation. In fact Dwyer does not teach combining laser light from multiple lasers at all.

In contrast to the teachings of Dwyer, the instant invention is directed to a laser system that is capable of operating in an ablation mode and a coagulation mode by using two or more pulsed laser sources, wherein pulses from each of the laser sources are combined to deliver a series of laser pulses for ablating tissue or coagulating tissue. Each of the independent Claims 1, 11, 17 and 41 recite the features of combining laser pulses from two or more laser sources.

Specifically, the independent Claim 1 is directed to medical laser delivery apparatus for delivering a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in

order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, each for generating laser pulses to provide the series of laser pulses and sufficient to generate ablation when the laser source is in an ablation mode. As discussed above, Dwyer does not teach or suggest a medical laser for delivering a series of laser pulses comprising combined laser pulses from two or more lasers. For at least these reasons, the independent Claim 1 is allowable over the teachings Dwyer.

Claim 2 is dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Dwyer. Accordingly, Claim 2 is also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating pluses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, Dwyer does not teach or suggest a medical laser with a laser source having two or more pulsed lasers for generating pluses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. For at least these reasons, the independent Claim 11 is allowable over the teachings of Dwyer.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to alternate between laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration, a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and

duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, Dwyer does not teach or suggest a medical laser delivery apparatus with a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to alternate between laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. For at least these reasons, the independent Claim 17 is allowable over the teachings of Dwyer.

Rejections Under 35 U.S.C. § 103

Within the previous Office Action, Claims 1-3, 6-8, 11-14, 17-19 and 43-49 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin"), Dwyer and the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson").

The teachings of Sklar are applied as the primary reference in a U.S.C. 103(a) rejection of Claims 1-3, 6-8, 11-14, 17-19 and 43-49 in the instant application. The teachings of Sklar have been fully characterized in previous communications. Briefly, the teachings of Sklar are directed to a system and method for accurately controlling and positioning laser sources, specifically during surgery. According to Sklar "a limiting factor to the duration of the operation under these procedures (viz. Prior Art procedures) is the surgeon's reaction time while focusing on the target and the patients movement while the surgeon is trying to find the target and react to the target recognition by firing the laser. [Sklar, column 5, lines 13-19] In view of these prior art limitations, Sklar teaches a system for performing precision laser surgery which includes an imaging system for providing a surgeon with precision tracking and topographical information regarding the surgical target area. [Sklar, Abstract] Sklar states that it is well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to efficiently use the laser. [Sklar, column 2, lines 39-43]

Sklar does not teach a laser device, or a laser system, with a laser source having two or more pulsed lasers, wherein pulses from the two or more pulsed lasers are alternated and combined to generate a single laser output as currently recited in each of the Independent Claims

1, 11 and 17. Nor does Sklar teach a laser device, or a laser system, for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Sklar does not teach an articulated arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49.

Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is coaligned with the infrared beam of the laser 20. Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue.

Dew does not teach a laser source with two or more lasers that produce laser beams that are alternated and combined to generate a single laser output as currently recited in each of the Independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Dew does not teach an articulated arm for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Dew teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Belkin teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin, col. 2, lines 35-44] Belkin does not teach a medical laser with a laser source with two or more pulsed, wherein pulses from each of the lasers are combined from generating a series of laser pulses as currently recited the independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Belkin does not teach an articulated arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Belkin teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Anderson teaches a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson, p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson, p. 524] Anderson does not teach a medical laser with a laser system as currently claimed. Specifically,

Anderson does not teach laser source with two or more lasers that produce pulses which are alternated or combined to generate a single laser output as currently recited in each of the Independent Claims 1, 11 and 17, or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Anderson does not teach an articulated arm for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Anderson teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

In contrast to the teachings of Sklar, Dew, Anderson, Belkin and Dwyer, the current invention is a laser system that utilizes multiple lasers. The lasers are preferably pulsed lasers. The pulses from the lasers are alternated or combined into a single laser output or series of pulses with a galvanometer or other suitable device to selectively generate the conditions for ablation or coagulation. The single laser output is preferably guided to a target tissue through an articulated arm with a series of refocussing optics. The system preferably has a user interface that allows a user to select laser pulse patterns, target sizes and operating modes. The interface preferably is a graphical user interface that displays the selected laser pulse pattern and allows the user to select a desired ablation depth value and coagulation depth value. The combinations of features claimed in the instant application are neither taught or suggested by Sklar, Dew, Belkin, Anderson nor their combination.

The independent Claim 1 is directed to medical laser delivery apparatus for delivering a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, each for generating laser pulses to provide the series of laser pulses and sufficient to generate ablation when the laser source is in an ablation mode. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser for delivering a series of laser pulses comprising combined laser pulses from two or more lasers. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 2, 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer

and their combination. Accordingly, Claims 2, 3 and 6-8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating pluses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser with a laser source having two or more pulsed lasers for generating pulses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. For at least these reasons, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to alternate between laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for generating a series of laser pulses each having a strength and a duration, a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser delivery apparatus which has two or more lasers which are combined in an

alternating fashion into a single laser output and a control system coupled for controlling the laser source for generating laser pulses with the strength and duration for both ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 18 and 19 are both allowable as being dependent upon an allowable base claim.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set laser pulses, means to alternate between pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output and means to direct the single laser output to the region of the target tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser delivery apparatus having first laser and a second laser for generating a first set of laser pulses and a second set laser pulses alternate to provide a single laser output. For at least these reasons, the new independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 42-49 all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 42-49 are all allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 4, 5, 9, 10, 20-24 and 42 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Sklar in combination with Dew, Anderson, Belkin and Dwyer, and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa"). Assa teaches an apparatus for delivering energy with a continuous output.

Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 4, 5, 9 and 10 are all also allowable as being dependent upon an allowable base claim.

Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer

and their combination. Accordingly, Claims 20-24 are all also allowable as being dependent upon an allowable base claim.

Claim 42 is dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claim 42 is also allowable as being dependent upon an allowable base claim.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (408) 530-9700 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
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Version of Amended Claims with Markings to Show Changes Made:

Please amend Claims 1-4, 11, 17, 23 and 41 as follows

1. (Four Times Amended) A medical laser delivery apparatus for delivering [one or more] a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating [a] the series of [one or more] laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, each for generating [two or more corresponding] laser [beams] pulses [which are alternated to produce a single laser output which] to provide[s] the series of [one or more non-ablative] laser pulses and sufficient to generate ablation when the laser source is in an ablation mode.

2. (Twice Amended) The medical laser delivery apparatus as claimed in claim 1 wherein the [single laser output is] series of laser pulses are focussed to the target tissue through an articulated arm feature.

3. (Twice Amended) The medical laser delivery apparatus as claimed in claim 2 wherein the [arm feature is an] articulated arm feature [and] comprises one or more refocussing optics for refocussing the laser pulses as they travel through the articulated arm feature.

4. (Twice Amended) The medical laser delivery apparatus as claimed in claim 3 wherein the laser delivery system further comprises a scanning handpiece at an end of the articulated arm feature for guiding the series of one or more non-ablative laser pulses to the area of tissue being treated.

11. (Four Times Amended) A medical laser comprising:
a. a laser source having two or more pulsed lasers for generating pulses of laser light, wherein the pulses of laser light [which] are combined in an alternating

4 fashion for generating a laser output having a predetermined absorption, wherein
5 the predetermined absorption forms a predetermined coagulation depth; and
6 b. a laser control system coupled to the laser source for controlling the laser source
7 [to generate a plurality of coagulative laser pulses from the laser output, such that
8 each such coagulative laser pulse is delivered in sequence] to deliver the laser
9 output to a target area.

1 17. (Four Times Amended) A medical laser delivery apparatus for treating an area of tissue
2 comprising:

- 3 a. a laser source having a first laser and a second laser [two or more lasers] each of
4 which generate laser pulses having a wavelength, [that are combined in an
5 alternating fashion] the laser source being configured to alternate between laser
6 pulses of the first laser and the second laser to form [into] a single laser output by
7 a combining apparatus for generating a series of [one or more] laser pulses each
8 having a strength and a duration;
9 b. a laser delivery system coupled to the laser source for delivering the laser pulses
10 from the laser source to the area of tissue being treated; and
11 c. a control system coupled to the laser source for controlling generation of the laser
12 pulses from the laser source, wherein the laser source operates in both an ablation
13 mode and a coagulation mode such that when in the ablation mode, the strength
14 and duration of the laser pulses are sufficient to ablate tissue at the area of tissue
15 being treated to a controllable ablation depth and when in the coagulation mode,
16 the strength and duration of the laser pulses are sufficient to generate a
17 coagulation region having a controllable coagulation depth within the tissue
18 remaining at the area of tissue being treated without ablating any tissue.

1 23. (Four Times Amended) The medical laser delivery apparatus as claimed in claim 22,
2 wherein the [two or more] first and second lasers are erbium lasers.

1 41. (Amended) A dual mode medical laser system, for sequentially ablating and coagulating a
2 region of target tissue with ablation laser pulses followed by coagulation laser pulses [to
3 the region of target tissue], the dual mode medical laser system comprising:

- 4 a. a laser source comprising a first laser and a second laser for generating a first
5 [laser beam] set of laser pulses and a second [laser beam] set of laser pulses [at a
6 same wavelength];
- 7 b. means to alternate between pulses of the first [laser beam] set of laser pulses and
8 the second [laser beam] set of laser pulses to provide a single laser output [to
9 provide the ablation laser pulses and the coagulation laser pulses]; and
- 10 c. means to direct the single laser output to the region of the target tissue.